K120195

510(k) SUMMARY
(as required by 807.92(c))

JUL 6 2012

Regulatory Correspondent:

AJW Technology Consultants
962 Allegro Lane
Apollo Beach, FL 33572
Tanya O'Brien
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813-645-2855
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Submitter of 510(k):

Multi Med Inc.
26 Victoria Court
Keene, NH, 03431, USA
Sue Starkey
sstarkey@multimedinc.com

Date of Summary: January 18, 2011

Trade/Proprietary Name: Safety Subcutaneous Tissue Infusion Set

Classification Name: Set, Administration, Intravascular

Product Code: FPA

Intended Use: The Safety Subcutaneous Infusion Set is designed specifically for the delivery of medications to the subcutaneous tissue.

Device Description: The safety subcutaneous needle infusion set consists of a sterile packaged kit including the infusion set and an adhesive dressing to hold the device in place. The unique Single, Bifurcated, Trifurcated, Quadfurcated, 5 and 6 Lumen for the Sub-Q have a luer lock at one end and a 90 degree needle mounted to a butterfly stabilizer at the other end. The sets are convenient to use, associated with less trauma, and offer an opportunity to improve compliance cost-effectively through the use of a dedicated infusion set. The device is for single use only.

Predicate Device:	Marcal Medical, Inc. K082818
Substantial Equivalence:	The Safety Subcutaneous Tissue Infusion Set is substantially equivalent in design and indications for use to Marcal Medical, Inc. K082818. They have the same indications for use. This device is substantially equivalent in design, material, intended use and function to the product listed as predicate devices.
Performance Testing:	Foreign Matter Tests (to Tappi Standards), Occlusion Test – no occlusions, Leak Test – no leaks, Safety Button Test – no failures.
Technical Comparison:	The proposed Multi Med Sub Q Safety Set and the predicate devices are identical in that they both consist of needle set with wings and needle safety feature. Both the proposed product and the predicate devices have been designed for subcutaneous infusions. Both the proposed and predicate devices are available in a variety of sizes. The needle safety feature of the proposed and predicate devices are identical and are functionally equivalent devices. Both the proposed and predicate devices are made of biocompatible materials and have the same technological design and identical in materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Multi Med, Inc.
Ms. Tanya O'Brien
Clinical Affairs Specialist
C/O AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, Florida 33572

JUL 6 2012

Re: K120195
Trade/Device Name: Safety Subcutaneous Tissue Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 29, 2012
Received: July 3, 2012

Dear Ms. O'Brien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

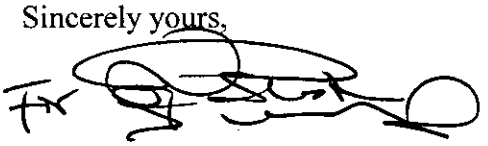
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120195

Device Name: Safety Subcutaneous Tissue Infusion Set - The Safety Subcutaneous Infusion Set is designed specifically for the delivery of medications to the subcutaneous tissue.

Prescription Use x (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

7/5/12

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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